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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/787,393

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Hiroyuki Sugiuchi

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01/15/2003

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EXAMINER

GITOMER, RALPH J

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 01/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/787,393**

Applicant(s)  
**Sugiuchi**

Examiner  
**Ralph Gitomer**

Art Unit  
**1651**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Dec 16, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-6, 8, 9, 12, 14, 15, 18-20, 22-24, and 27-41 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-6, 8, 9, 12, 14, 15, 18-20, 22-24, and 27-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

5 The amendments of 10/16/02 and 12/16/02 have been entered  
and claims 2-6, 8-9, 12, 14-15, 18-20, 22-24, 27-41 are currently  
pending in this application. The references of record do not  
fairly teach or suggest the presently claimed combination of  
enabling the enzymes to act only on LDL cholesterol by contacting  
with the combination of a polyoxyethylene derivative and a  
polyoxyethylene-polyoxypropylene copolymer.

10 The disclosure is objected to because of the following  
informalities, appropriate correction is required.

15 In claim 12 and all occurrences, the claims referred to may  
not be intended to be in parentheses. This is inconsistent and  
improper. The specification contains many instances of  
trademarked names. In all occurrences the generic terminology  
must accompany the capitalized trademark name. On page 16 line  
26, the number appears incomplete.

20 Claims 34-35 rejected under 35 U.S.C. 112, first paragraph,  
as containing subject matter which was not described in the  
specification in such a way as to reasonably convey to one  
skilled in the relevant art that the inventor(s), at the time the  
application was filed, had possession of the claimed invention.

New claim 34 is directed to enzymes that are not chemically modified. New claim 35 is directed to a surfactant that does not solubilize the aggregate lipoproteins. Negative limitations require the highest degree of enablement and the new limitations are not found in the specification as originally filed. Please provide specifically where in the specification as originally filed each and every limitation is found for all the newly added claims.

Claims 2-6, 8-9, 12, 14-15, 18-20, 22-24, 27-41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 2(c), 5(c) and all occurrences, ~~or~~ reduced coenzyme~~is~~ is unclear as to what may be intended because no oxidized enzyme or coenzyme of any sort that could be reduced is seen. In claim 6(I), ~~conducting~~ a first reaction cholesterol~~is~~ is not understood. In general, method steps should be properly stated as positively stated gerunds such as contacting, reacting, determining and correlating rather than subjecting or conducting. In claim 29 and all occurrences, ~~capable of~~ is indefinite as to what actually occurs. Suggested terminology is ~~chromogen~~ which produces a dye~~.~~.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-

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4556. Any inquiry of a general nature or relating to the status  
of this application should be directed to the Group receptionist  
whose telephone number is (703) 308-1235. For 24 hour access to  
patent application information 7 days per week, or for filing  
5 applications electronically, please visit our website at  
www.uspto.gov and click on the button Patent Electronic Business  
Center for more information.

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Ralph Gitomer  
Primary Examiner  
Group 1651

RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200